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February 19, 1988

Patent Law Department
American Cyanamid Company
1937 West Main Street
P.O. Box 60
Stamford, CT 06904-0060

#17

RE: Patent Term Extension Application
U.S. Patent 4,278,689

An application for patent term extension of U.S. Patent No. 4,278,689 which issued July 14, 1981, was filed on February 17, 1988. The basis for the application is said to be 35 USC 156. The application was filed on behalf of the patent owner American Cyanamid Company.

The application states that the patent claims the approved product, identified as NOVANTRONE, and that this product was subject to regulatory review under section 505 of the Federal Food, Drug and Cosmetic Act (21 USC 355). The product is said to have received permission for commercial marketing or use by the Food and Drug Administration on December 23, 1987.

The application for patent term extension described the approved product as NOVANTRONE, the single active ingredient therein being mitoxantrone hydrochloride (1,4-bis[2-(2-hydroxy-ethylamino) ethylamino]-5,8-dehydroxyanthraquinone dihydrochloride). Claims 1, 3, 12 and 18 are stated to encompass the approved product within the meaning of 35 USC 156. Claim 1, on which the remaining claims depend either directly or indirectly provides that the active ingredient mitoxantrone hydrochloride is present in a pharmaceutical composition of dosage unit form in an amount of about one to about 30 mg. in association with a pharmaceutical carrier. Applicant states that the approved product is embraced by or covered by each of the above identified claims. However, neither the patent nor applicant's statements have clearly demonstrated that the claims actually include or encompass the approved product within the meaning of 35 USC 156 as alleged since no information is provided which would indicate the amount of active ingredient which is present in the approved product.

The statutory provisions of 35 USC 156 permit extension of the patent term of a patent which claims a product or use thereof where that product has been subject to a regulatory review before its commercial marketing or use. Therefore, the term of U.S.

Patent 4,278,689 would not be eligible for extension under 35 USC 156 if at least one claim was not directed to the approved product, a method of manufacturing the approved product or a method of use thereof within the meaning of 35 USC 156. It is not clear from the application filed February 17, 1988, how U.S. Patent No. 4,278,689 should be considered to claim the approved product or use thereof.

Applicant is given a period of ONE(1) MONTH FROM THE DATE OF THIS LETTER in which to file the information described above. Applicant is reminded that such a response to this letter is not subject to extensions of time for response provisions of 37 CFR 1.136(a).

Response to this letter must be directed to:

Commissioner of Patents and Trademarks
Box Patent Ext.
Washington, DC 20231

/Douglas W. Robinson/
Douglas W. Robinson
Primary Examiner
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment and Policy Staff
Office of Health Affairs (HFY-20)
Room 11-46
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

E: NOVANTRONE
(Mitoxantrone hydrochloride)